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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,148	10/02/2001	Robert Kisilevsky	NC1-043CN	2661

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	7

DATE MAILED: 04/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/970,148	KISILEVSKY ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- Th MAILING DATE of this communication app ars on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-54 and 56-67* is/are rejected.

7)☒ Claim(s) *55* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 June 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The disclosure is objected to because of the following informalities: The claim for priority under 35 U.S.C. 120 inserted by the preliminary amendment filed October 2, 2001 and the claim for priority under 35 U.S.C. 119(e) at page 1, lines 4-6, of the specification need to be re-written as a single sentence. Also, the status of the parent non-provisional application should be updated. Appropriate correction is required.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60, 61, and 63-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure of inhibiting the binding of chemokines in general as is recited in instant claim 60. The disclosure of a few species of chemokines, as at the bottom of page 5 and Figures 15-28 cited by Applicants, does not provide written descriptive support for the entire genus of chemokines.

3. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 64, lines 10 and 12, the word "and" should be deleted so that standard Markush terminology is used.

4. Claims 64 and 65 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or

rewrite the claim(s) in independent form. Not all of the compounds recited in dependent claims 64 and 65 contain the particular Y groups required by the formula recited in independent claim 60. Examples are the methylene diphosphonic acid recited in claim 64, and the trisodium phosphonoformate, nitrilo(methylene) triphosphonic acid, O-phospho-L-serine, and 2-thiopheneboronic acid recited in claim 65.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 47-49 and 60-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,310,073. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '073 patent anticipate instant claims 60-64. Because the same active agent is being administered to the same subject in the claimed method of the '073 patent as in the instant claimed method, inherently the binding of chemokines to glycosaminoglycans will be inhibited in the claimed method of the '073 patent to the same extent claimed in instant claims 60-64. With respect to instant claim 47-49, while the '073 patent does not claim its active agents in combination with pharmaceutically acceptable carriers, it would have been obvious to one of ordinary skill in the art to combine the active agents recited in the claims of the '073 patent with

pharmaceutically acceptable carriers because active agents are routinely combined with pharmaceutically acceptable carriers in the pharmaceutical arts for ease of storage, transportation, measurement, and administration.

6. Instant claims 45-59, 66, and 67 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/094,454 because the '454 application, under the test of 35 U.S.C. 112, first paragraph, discloses the instant claimed invention.

Instant claims 60-65 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/094,454 because the '454 application, under the test of 35 U.S.C. 112, first paragraph, does not disclose inhibiting the binding of chemokines in general or of RANTES, Eotaxin, or IL-8 in particular, and does not disclose the active agents recited in instant claim 65.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

8. Claims 47, 48, and 60-63 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 90/08541. The WO Patent Application '541 teaches treating metastatic adrenocortical cancer by administering suramin, which inhibits the molecular interaction between lysosomal enzymes and glycosaminoglycans. Suramin comprises plural sulfonate groups attached to an aromatic carrier. The suramin can be administered in combination with a pharmaceutically acceptable carrier. See, e.g., the Abstract; page 1, lines 4-12; and page 22, lines 18-30. Note that Applicants have defined aromatic groups at page 16, lines 16-17, of their specification as embracing substituted aromatic groups. With respect to instant claims 47 and 48, note that an intended use limitation does not impart patentability to product claims where the

product is otherwise anticipated by the prior art. With respect to instant claims 60-63, because the same active agent is being administered to the same subject in the WO Patent Application '541 as in the instant claimed method, and because the WO Patent Application '541 discloses that its method involves interfering with GAG interactions, inherently the binding of chemokines to glycosaminoglycans will be inhibited in the WO Patent Application '541 to the same extent claimed in instant claims 60-63. Sufficient evidence of similarity is deemed to be present between the WO Patent Application '541 and Applicants' claimed invention to shift the burden to Applicants to provide evidence that their claimed invention is unobviously different than that of the WO Patent Application '541.

9. Claims 45 and 46 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 90/08541. Application of the WO Patent Application '541 is the same as in the above rejection of claims 47, 48, and 60-63. The WO Patent Application '541 does not teach packaging the suramin in combination with instructions for use. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to package the suramin of the WO Patent Application '541 in combination with instructions for use because all drugs intended for therapeutic use are required to be packaged with instructions for use. As to the substance of the text which is present in the instructions of use, the examiner is not aware of any case law holding that such text can be relied upon to impart patentability to composition claims because the substance of the text does not impose any structural or functional limitations on the composition.

10. Claims 47-49 and 60-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Kisilevsky et al (U.S. Patent No. 5,643,562). Kisilevsky et al '562 teach inhibiting amyloid

deposition by administering compounds which inhibit the molecular interaction between amyloidogenic protein and glycosaminoglycans. The compounds are the same as those claimed by Applicants, e.g., the compounds can be aliphatic-based such as 1,3-propanedisulfonic acid. The compounds can be administered in combination with a pharmaceutically acceptable vehicle. Amyloid deposition is defined to include bovine spongiform encephalitis and other prion protein-based diseases. See, e.g., the Abstract; column 1, lines 33-37; column 3, lines 44-56; the Examples; and claims 1-55. With respect to instant claims 47-49, note that an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art. With respect to instant claims 60-64, because the same active agent is being administered to the same subject in Kisilevsky et al '562 as in the instant claimed method, and because Kisilevsky et al '562 discloses that its method involves interfering with GAG interactions, inherently the binding of chemokines to glycosaminoglycans will be inhibited in Kisilevsky et al '562 to the same extent claimed in instant claims 60-64. Sufficient evidence of similarity is deemed to be present between Kisilevsky et al '562 and Applicants' claimed invention to shift the burden to Applicants to provide evidence that their claimed invention is unobviously different than that of Kisilevsky et al '562.

11. Claims 45, 46, and 49 are rejected under 35 U.S.C. 103(a) as being obvious over Kisilevsky et al (U.S. Patent No. 5,643,562). Application of Kisilevsky et al '562 is the same as in the above rejection of claims 47-49 and 60-64. Kisilevsky et al '562 does not teach packaging the compounds in combination with instructions for use. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to package the compounds of Kisilevsky et al '562 in combination with instructions for use because all drugs intended for

therapeutic use are required to be packaged with instructions for use. As to the substance of the text which is present in the instructions of use, the examiner is not aware of any case law holding that such text can be relied upon to impart patentability to composition claims because the substance of the text does not impose any structural or functional limitations on the composition.

12. Claims 47, 48, 51, 54, 56, 57, 59-63, 66, and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Cardin et al (U.S. Patent No. 5,494,932). Cardin et al teach treating HIV, CMV, and HSV infections by administering compounds comprising two sulfonic acid groups. The compounds are administered in combination with pharmaceutically acceptable carriers. See, e.g., column 4, lines 61-65; column 7, line 37 - column 8, line 46; and claims 1-4. The carrier portion of Cardin et al's compounds is comprises an aromatic group and an aliphatic group. Note that Applicants have defined aliphatic groups at page 15, lines 2-4, of their specification as embracing substituted aliphatic groups and have defined aromatic groups at page 16, lines 16-17, of their specification as embracing substituted aromatic groups. Cardin et al's compounds have the same structure required by the formula recited in Applicants' claims 47, 48, 51, 54, 59, and 60. Because the same viral infections are being treated in the same subject with a compound having the same structural formula in both Cardin et al and Applicants' claimed invention, inherently a glycosaminoglycan-associated molecular interaction will be modulated and an interaction between the viruses and a cell surface will be inhibited in the method of Cardin et al to the same extent claimed by Applicants. Note that patentability can not be based merely upon the employment of descriptive language not chosen by the prior art (In re Skoner, 186 USPQ 80, 82 (CCPA 1975)), and can not be based merely upon the provision of a fuller scientific explanation of what inherently occurs in a prior art method (In re King, 231 USPQ 136, 139

(CAFC 1986)). With respect to instant claim 48, note that an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art. With respect to instant claims 60-63, because the same active agent is being administered to the same subject in Cardin et al as in the instant claimed method, inherently the binding of chemokines to glycosaminoglycans will be inhibited in Cardin et al to the same extent claimed in instant claims 60-63. Sufficient evidence of similarity is deemed to be present between Cardin et al and Applicants' claimed invention to shift the burden to Applicants to provide evidence that their claimed invention is unobviously different than that of Cardin et al.

13. Claims 45 and 46 are rejected under 35 U.S.C. 103(a) as being obvious over Cardin et al (U.S. Patent No. 5,494,932). Application of Cardin et al is the same as in the above rejection of claims 47, 48, 51, 54, 56, 57, 59-63, 66, and 67. Cardin et al do not teach packaging the compounds in combination with instructions for use. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to package the compounds of Cardin et al in combination with instructions for use because all drugs intended for therapeutic use are required to be packaged with instructions for use. As to the substance of the text which is present in the instructions of use, the examiner is not aware of any case law holding that such text can be relied upon to impart patentability to composition claims because the substance of the text does not impose any structural or functional limitations on the composition.

14. Claims 47, 48, and 60-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Umezawa et al (U.S. Patent No. 4,091,202). Umezawa et al teach treating S. aureus and P. aeruginosa infections by administering 3',4'-dideoxykanamycin B derivatized with N-methanesulfonic acid groups. The compounds are administered in combination with

pharmaceutically acceptable carriers. See, e.g., column 2, line 10 - column 3, line 3; Table 1; and column 5, lines 17-53. The methane group in the N-methanesulfonic acid group of Umezawa et al's compounds is deemed to constitute an aliphatic group. Note that Applicants have defined aliphatic groups at page 15, lines 2-4, of their specification as embracing substituted aliphatic groups. Umezawa et al's compounds have the same structure required by the formula recited in Applicants' claims 47, 48, and 60. With respect to instant claims 47 and 48, note that an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art. With respect to instant claims 60-63, because the same active agent is being administered to the same subject in Umezawa et al as in the instant claimed method, inherently the binding of chemokines to glycosaminoglycans will be inhibited in Umezawa et al to the same extent claimed in instant claims 60-63. Sufficient evidence of similarity is deemed to be present between Umezawa et al and Applicants' claimed invention to shift the burden to Applicants to provide evidence that their claimed invention is unobviously different than that of Umezawa et al.

15. Claims 45 and 46 are rejected under 35 U.S.C. 103(a) as being obvious over Umezawa et al (U.S. Patent No. 4,091,202). Application of Umezawa et al is the same as in the above rejection of claims 47, 48, and 60-63. Umezawa et al do not teach packaging the compounds in combination with instructions for use. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to package the compounds of Umezawa et al in combination with instructions for use because all drugs intended for therapeutic use are required to be packaged with instructions for use. As to the substance of the text which is present in the instructions of use, the examiner is not aware of any case law holding that such text can be relied

upon to impart patentability to composition claims because the substance of the text does not impose any structural or functional limitations on the composition.

16. Claims 47, 48, and 60-63 are rejected under 35 U.S.C. 102(a) as being anticipated by the West Derwent Abstract. The West Derwent Abstract teaches an aerosol form of a compound having chlamydostatic action. The compound comprises a methanesulphonic acid group. The methane group in the N-methanesulfonic acid group of the West Derwent Abstract's compound is deemed to constitute an aliphatic group. Note that Applicants have defined aliphatic groups at page 15, lines 2-4, of their specification as embracing substituted aliphatic groups. The West Derwent abstract's compound has the same structure required by the formula recited in Applicants' claims 47, 48, and 60. With respect to instant claims 47 and 48, note that an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art. With respect to instant claims 60-63, because the same active agent is being administered to the same subject in the West Derwent Abstract as in the instant claimed method, inherently the binding of chemokines to glycosaminoglycans will be inhibited in the West Derwent Abstract to the same extent claimed in instant claims 60-63. Sufficient evidence of similarity is deemed to be present between the West Derwent Abstract and Applicants' claimed invention to shift the burden to Applicants to provide evidence that their claimed invention is unobviously different than that of the West Derwent Abstract.

17. Claims 45-48, 50, 52, 53, and 58 are rejected under 35 U.S.C. 103(a) as being obvious over the West Derwent abstract. Application of the West Derwent abstract is the same as in the above rejection of claims 47, 48, and 60-63. The West Derwent abstract does not teach treating Chlamydia trachomatis infections specifically, and does not teach packaging the compounds in

combination with instructions for use. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to treat Chlamydia trachomatis infections specifically using the active agent of the West Derwent abstract because Chlamydia trachomatis is the most common Chlamydia species found in humans and it is desirable to treat such infections, and because agents active against chlamydia in general would have been expected to be active against Chlamydia trachomatis specifically. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to package the compounds of the West Derwent abstract in combination with instructions for use because all drugs intended for therapeutic use are required to be packaged with instructions for use. As to the substance of the text which is present in the instructions of use, the examiner is not aware of any case law holding that such text can be relied upon to impart patentability to composition claims because the substance of the text does not impose any structural or functional limitations on the composition.

18. Claim 65 is rejected under 35 U.S.C. 102(b) as being anticipated by the Helgstrand et al article (Reference C4 of the Information Disclosure Statement filed March 14, 2003). The Helgstrand et al article teaches in vivo administration of trisodium phosphonoformate (i.e. foscarnet sodium) to guinea pig infected with HSV. See, e.g., page 1359, column 1. Because the same active agent is being administered to the same subject in the Helgstrand et al article as in the instant claimed method, inherently the binding of chemokines to glycosaminoglycans will be inhibited in the Helgstrand et al article to the same extent claimed in instant claim 65. Sufficient evidence of similarity is deemed to be present between the Helgstrand et al article and

Applicants' claimed invention to shift the burden to Applicants to provide evidence that their claimed invention is unobviously different than that of the Helgstrand et al article.

19. Claims 47, 48, 51, 54, 56, 57, 59-63, 66, and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Gulliya et al (U.S. Patent No. 5,091,385). Gulliya et al teach pre-activated merocyanine 540, which comprises a sulfopropyl group, for use in treating infections by viruses such as herpes simplex virus, cytomegalovirus, and HIV. The active agent is mixed with a pharmaceutically acceptable carrier or vehicle. See, e.g., column 1, lines 7-14; column 10, liens 4-48; column 11, lines 52 and 57-59; column 12, lines 13-15; and Table 14. Gulliya et al's compounds have the same structure required by the formula recited in Applicants' claims 47, 48, 51, 54, 59, and 60. Because the same viral infections are being treated in the same subject with a compound having the same structural formula in both Gulliya et al and Applicants' claimed invention, inherently a glycosaminoglycan-associated molecular interaction will be modulated and an interaction between the viruses and a cell surface will be inhibited in the method of Gulliya et al to the same extent claimed by Applicants. Note that patentability can not be based merely upon the employment of descriptive language not chosen by the prior art (In re Skoner, 186 USPQ 80, 82 (CCPA 1975)), and can not be based merely upon the provision of a fuller scientific explanation of what inherently occurs in a prior art method (In re King, 231 USPQ 136, 139 (CAFC 1986)). With respect to instant claim 48, note that an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art. With respect to instant claims 60-63, because the same active agent is being administered to the same subject in Gulliya et al as in the instant claimed method, inherently the binding of chemokines to glycosaminoglycans will be inhibited in Gulliya et al to the same extent claimed

in instant claims 60-63. Sufficient evidence of similarity is deemed to be present between Gulliya et al and Applicants' claimed invention to shift the burden to Applicants to provide evidence that their claimed invention is unobviously different than that of Gulliya et al.

20. Claims 45 and 46 are rejected under 35 U.S.C. 103(a) as being obvious over Gulliya et al (U.S. Patent No. 5,091,385). Application of Gulliya et al is the same as in the above rejection of claims 47, 48, 51, 54, 56, 57, 59-63, 66, and 67. Gulliya et al do not teach packaging the compounds in combination with instructions for use. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to package the compounds of Gulliya et al in combination with instructions for use because all drugs intended for therapeutic use are required to be packaged with instructions for use. As to the substance of the text which is present in the instructions of use, the examiner is not aware of any case law holding that such text can be relied upon to impart patentability to composition claims because the substance of the text does not impose any structural or functional limitations on the composition.

21. Claim 55 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record does not teach or suggest administering the active agents recited in this claim to subjects infected with a virus or with the bacteria specified in instant claims 50-52 and 54. While Kisilevsky et al (U.S. Patent No. 5,643,562) teach the claimed active agents, Kisilevsky et al do not teach or suggest the therapeutic methods of claim 55.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

April 17, 2003